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10/585,693	11/09/2006	Takashi Yamashita	Q95455	4348
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EXAMINER				
WILSON, MICHAEL C				
ART UNIT		PAPER NUMBER		
1632				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary

Application No.

10/585,693

Applicant(s)

YAMASHITA ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-23 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Examiner of this application has changed. Please send future correspondences to Examiner Michael C. Wilson, Art Unit 1632.

Applicant's arguments filed 6-25-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2 and 24-27 has been canceled. Claims 1, 3-23, 28-30 are pending.

Election/Restrictions

This application contains claims 7-23, and 28-30, drawn to an invention nonelected with traverse in the reply filed on 12-28-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1 and 3-6 are under consideration.

Claim Objections

Claim 1 is objected to because the first step (a) should be "incubating...".

Claim 1 is objected to because the "microinjecting" step uses improper grammar (inverse copular construction). The phrase "into the early embryo" should be the prepositional phrase at the end of the sentence, i.e. --microinjecting a replication-deficient retroviral vector coding for a protein into an avian embryo after...-- is grammatically correct.

Claim Rejections - 35 USC § 112

New Matter

The rejection regarding claims 25-27 under 35 U.S.C. §112, first paragraph, new matter, has been withdrawn because the claims have been canceled.

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "the early embryo thereof" in claim 1 lacks antecedent basis. The "fertilized avian embryo" mentioned prior in the claim does not necessarily have an early embryo; therefore, the phrase may not occur. Clarification is required.

Claim 1 is indefinite because "at a stage except for and after the blastodermic stage just after egg laying... ..wherein the early embryo is at least 24 after the start of incubation" lacks a nexus. Step a) (which is actually step b) should clearly include the "24 hours after" limitation and somehow clearly refer to the "stage" and (possibly) the "stage" should clearly refer to the "start of incubation." More specifically, it appears that step a) says the microinjection occurs after the stage when the egg has been laid (Stage X), but the last phrase appears to indicate the microinjection occurs 24 hours after the egg has been laid. The two phrases should have a nexus. Clarification is required.

Claim Rejections - 35 USC § 102

The rejection of claims 25-27 under 35 U.S.C. 102(e) as being anticipated by Ransohoff (U.S. Patent Application Publication 2003/0176660; effective filing date Feb. 8, 2002) has been withdrawn because the claims have been canceled.

Upon further consideration, the following rejections have been made:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, and 6 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Harvey (Nature Biotechnology, April 2002, Vol. 19, pg 396-399).

Harvey taught a transgenic G1 chicken obtained by microinjecting a Stage X early embryo with a replication-defective retroviral vector encoding a protein, allowing the embryo to develop to term and hatch, thereby obtaining a G0 chick, mating the G0 chick after reaching sexual maturity. The phrase "at a stage except for and after the blastodermic stage just after egg laying" is met by Harvey because Stage X is "after the

blastodermic stage just after egg laying" and because the phrase "except for and after the blastodermic stage" encompasses a "stage... ..after the blastodermic stage just after laying".

Furthermore, and more importantly, the timing of when the vector is injected, i.e. Stage X vs. Stage XI (or later), does not distinguish the structure of the transgenic chicken claimed or made by applicants from the transgenic chicken described by Harvey. Therefore, the transgenic chicken described by Harvey has the same structure as a transgenic chicken injected at Stage XI, 24 hours after being laid (possibly implied by the last phrase of claim 1 - "wherein the early embryo is at least 24 hours after the start of incubation"), 48 hours after being laid (possibly implied by the limitation of claim 3 - "wherein the early embryo is at least 48 hours after the start of incubation") as claimed and has the same structure as the transgenic chicken disclosed by applicants.

Claim 6 has been included because Harvey taught G2 chickens, which inherently have the same structure as the G2 chickens disclosed by applicants and encompassed by claim 6.

Claims 1, 3, 5, and 6 are newly rejected under 35 U.S.C. 102(a) as being anticipated by Rapp (Transgenic Res., Oct. 2003, Vol. 12, pg 569-575) as supported by Speksnijder (2000, Poultry Sci., Vol. 79, pg 1430-1433).

Rapp taught a transgenic G1 chicken obtained by microinjecting the subgerminal cavity of chicken embryos with a replication-defective retroviral vector encoding a protein, allowing the embryo to develop to term and hatch, thereby obtaining a G0 chick,

mating the G0 chick after reaching sexual maturity and obtaining G1 chickens expressing the protein. Rapp used the method of Speksnijder for injection (pg 530, "Generation of transgenic chickens"), which requires injecting "fresh, fertile eggs" (pg 1431, col. 1, "Windowing and Injecting Eggs", line 1) which at least equivalent to injecting Stage X eggs.

The phrase "at a stage except for and after the blastodermic stage just after egg laying" is met by Rapp because Stage X is "after the blastodermic stage just after egg laying" and because the phrase "except for and after the blastodermic stage" encompasses a "stage... ..after the blastodermic stage just after laying". Furthermore, and more importantly, the timing of when the vector is injected, i.e. Stage X vs. Stage XI, does not distinguish the structure of the transgenic chicken claimed or made by applicants from the transgenic chicken described by Rapp. Therefore, the transgenic chicken described by Rapp has the same structure as a transgenic chicken injected at Stage XI, 24 hours after being laid (possibly implied by the last phrase of claim 1 - "wherein the early embryo is at least 24 hours after the start of incubation"), or 48 hours after being laid (possibly implied by the limitation of claim 3 - "wherein the early embryo is at least 48 hours after the start of incubation") as claimed and has the same structure as the transgenic chicken disclosed by applicants.

Claim 6 has been included because Rapp taught G2 chickens, which inherently have the same structure as the G2 chickens disclosed by applicants and encompassed by claim 6.

Claims 1, 3-6 are newly rejected under 35 U.S.C. 102(e) as being anticipated by MacArthur (US Patent 6,825,396).

MacArthur taught a transgenic chicken comprising a transgene encoding interferon alpha or erythropoietin (claim 1). The chickens described by MacArthur were made using a REV vector comprising an ovalbumin promoter and a lysozyme signal sequence (Fig. 2; claim 1). MacArthur also taught the vector could encode antibodies, factor VIII, G-CSF, and immunoreactive proteins (i.e. immunotoxins) et al. (col. 4, lines 36-55). The retrovirus was injected into freshly laid egg embryos (Stage X; col. 14, line 60-65).

The phrase "at a stage except for and after the blastodermic stage just after egg laying" is met by MacArthur because Stage X is "after the blastodermic stage just after egg laying" and because the phrase "except for and after the blastodermic stage" encompasses a "stage... ..after the blastodermic stage just after laying". Furthermore, and more importantly, the timing of when the vector is injected, i.e. Stage X vs. after Stage X, does not distinguish the structure of the transgenic chicken claimed or made by applicants from the transgenic chicken described by MacArthur. Therefore, the transgenic chicken described by MacArthur has the same structure as a transgenic chicken injected at Stage XI, 24 hours after being laid (possibly implied by the last phrase of claim 1 - "wherein the early embryo is at least 24 hours after the start of incubation"), or 48 hours after being laid (possibly implied by the limitation of claim 3 - "wherein the early embryo is at least 48 hours after the start of incubation") as claimed and has the same structure as the transgenic chicken disclosed by applicants.

Claim 6 has been included because MacArthur taught G2 chickens, which inherently have the same structure as the G2 chickens disclosed by applicants and encompassed by claim 6.

Claims 1, 3-6 newly are rejected under 35 U.S.C. 102(e) as being anticipated by Ivarie (US Patent 6,730,822).

Ivarie taught a G1 transgenic chicken comprising a transgene encoding an exogenous protein (col. 25, line 30). The chickens described by Ivarie were made using replication-defective retrovirus (col. 19, line 52) and could encode antibodies (col. 19, line 39). The retrovirus was injected into early egg embryos (Stage VII-XII; col. 11, line 38).

The phrase "at a stage except for and after the blastodermic stage just after egg laying" is met by MacArthur because Stage X is "after the blastodermic stage just after egg laying" and because the phrase "except for and after the blastodermic stage" encompasses a "stage... ..after the blastodermic stage just after laying". Furthermore, and more importantly, the timing of when the vector is injected, i.e. Stage X vs. after Stage X, does not distinguish the structure of the transgenic chicken claimed or made by applicants from the transgenic chicken described by MacArthur. Therefore, the transgenic chicken described by MacArthur has the same structure as a transgenic chicken injected at Stage XI, 24 hours after being laid (possibly implied by the last phrase of claim 1 - "wherein the early embryo is at least 24 hours after the start of incubation"), or 48 hours after being laid (possibly implied by the limitation of claim 3 -

"wherein the early embryo is at least 48 hours after the start of incubation") as claimed and has the same structure as the transgenic chicken disclosed by applicants.

Claim 6 has been included because MacArthur taught G2 chickens, which inherently have the same structure as the G2 chickens disclosed by applicants and encompassed by claim 6.

Claims 1 and 3-6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sang (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi (Development 125:2521-2532; 1998) for reasons of record.

Sang taught transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Replication defective vectors, such as ALV and other lentiviruses are taught in paragraph [0013], on p. 2 and paragraph [0017], p. 3. Lentiviruses are described as a subgroup of the retroviruses (paragraph [0015], p. 3). Sang specifically taught obtaining fertile hen's eggs containing developing chick embryos at developmental stages X-XIII ; and injection of VSV-G pseudotyped lentiviral vector into the subgerminal cavity below the embryo (Experiment 1, paragraph [0064], p. 5), to produce G0 transgenic chickens (paragraph [0090], p. 7). Stage 13 chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary; limitation of claims 1 and 3). Germ line transmission from G0 males and breeding by crossing to stock hens and screening

their G1 offspring is described in paragraph [0092], p. 7. The analysis of G1 transgenic birds and transmission to G2 from the founder birds is described in paragraphs [0093-0095], p. 7 (limitation of claim 6). Transgene expression in G1 and G2 transgenic birds is taught in paragraph [0096], pp. 7-8. Sang taught the transgene material may encode any of a large number of proteins, and may include sequences encoding antibodies (paragraph [0030], p. 4; limitation of claim 4).

Response to arguments

Applicants' argue Sang did not teach " 24 hours after the start of incubation." Applicants' argument is not persuasive. Stage XIII is 24 hours after the start of incubation. Furthermore, the process step claimed does not distinguish a transgenic chicken made by Sang by injection at Stage X from one made by applicants by injection 24 hours after incubation (after being laid at stage X). If Stage XIII is within 24 hours after Stage X (a freshly laid egg), clarification is required what stages are encompassed/excluded from the phrase "at least 24 hours after the start of incubation" and how the structure of a transgenic avian made by injection "at least 24 hours after the start of incubation" differs from a transgenic chicken made by injection at Stage X or XIII.

Overall, the burden is placed upon the applicants to establish a patentable distinction between the claimed and referenced products. The method in which the transgenic chickens were produced as claimed does not distinguish them over the

transgenic chickens known in the art at the time of filing. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP §2113.

Claim Rejections - 35 USC § 103

The rejection of claims 1 and 3-6 under 35 U.S.C. 103(a) as being unpatentable over Sang (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi (Development 125:2521-2532; 1998), in view of Rapp (U.S. Patent Publication No. 2002/0108132, effective filing date Feb. 2, 2001) has been withdrawn because it was based on the limitation of using a retroviral vector derived from Moloney murine leukemia virus, which is no longer part of the claimed invention.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner